REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. Prior to the present amendment, claims 56-64 were pending and under consideration. By the present amendment, claims 56 and 61 are amended to more specifically recite certain aspects of the invention. Support for the amendment is provided throughout the specification and claims as filed, and the amendment does not constitute new matter. It should be noted that the above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application.

Petition Under 37 C.F.R. § 1.137(b)

Applicants thank the Examiner for acknowledging that the petition filed under 37 C.F.R. § 1.137(b) to withdraw abandonment has been granted and entering the amendment filed on October 2, 2003.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 56-64 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not being enabled by the instant specification. Specifically, the Action asserts that the instant specification, while being enabling for an isolated antibody or an antigen binding fragment thereof specific for a caspase-14 polypeptide comprising SEQ ID NO:2 or SEQ ID NO:5, does not reasonably provide enablement for antibodies specific for any and all fragments of SEQ ID NO:2 or SEQ ID NO:5.

Applicants respectfully traverse this basis of rejection and submit that the instant specification fully enables the skilled artisan to practice the full scope of the claimed invention. Nonetheless, without acquiescence to this basis of rejection and solely to expedite prosecution of the instant application, claims 56 and 61 have been amended to remove reference to fragments of polypeptides comprising SEQ ID NOs:2 or 5. Accordingly, the claims are now directed to antibodies and antigen binding fragments thereof specific for a caspase-14 polypeptide

comprising SEQ ID NO:2 or SEQ ID NO:5, which are clearly enabled by the instant specification, as indicated by the Examiner in the Office Action mailed January 7, 2004. In light of this amendment, Applicants respectfully request that the Examiner reconsider and withdraw this basis of rejection.

Rejections Under 35 U.S.C. § 103(a)

Claims 61-64 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rasmussen *et al.* More specifically, the Action asserts that Rasmussen *et al.* teaches an isolated polypeptide comprising a polypeptide sequence having greater than 80% identity with SEQ ID NO:5 and that it would have been *prima facie* obvious to one of ordinary skill in the art to produce an isolated antibody to this polypeptide once it was isolated, in light of the Board of Patent Appeals and Interferences' position that once an antigen is isolated, the manufacture of antibodies against it is *prima facie* obvious.

Applicants respectfully traverse this basis of rejection and submit that claims 61-64 are not obvious in light of Rasmussen *et al.*, since this reference fails to teach each element of the claimed invention. Applicants first note that claim 61 has been amended, without acquiescence to this basis of rejection, to recite the feature that the claimed antibodies are specific for a caspase-14 polypeptide comprising SEQ ID NO:5. The polypeptide sequence described by Rasmussen *et al.* is not a caspase-14 polypeptide comprising SEQ ID NO:5, so any antibodies produced against the polypeptide of Rasmussen *et al.* would clearly not be specific for a caspase-14 polypeptide comprising SEQ ID NO:5. Accordingly, Applicants submit that Rasmussen *et al.* fails to render the claimed antibodies (and cells expressing these antibodies) obvious and respectfully request that this basis of rejection be withdrawn.

Claims 56-60 stand similarly rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rasmussen *et al.* Specifically, the Action asserts that Rasmussen *et al.* teaches an isolated polypeptide that is nearly 70% identical to SEQ ID NO:2, which encompasses a fragment thereof of SEQ ID NO:2. Thus, the Action asserts it would have been *prima facie* obvious to one of ordinary skill in the art to produce an isolated antibody to the antigen identified by Rasmussen *et al.*, and one would have a reasonable expectation that such antibodies would

bind to a fragment thereof of SEQ ID NO:2 because of the high degree of amino acid similarity between the prior art polypeptide and SEQ ID NO:2. The Action also asserts that it would have been obvious to make both monoclonal and polyclonal antibodies and further obvious to include an isolated cell expressing a monoclonal antibody because the manufacture of such antibodies by the use of tumor-fused spleen cells was well known at the time the article was published.

Applicants respectfully traverse this basis of rejection and submit that claims 55-60 are not obvious in light of Rasmussen *et al.* Applicants first note that claim 55 has been amended, without acquiescence to this basis of rejection, to recite the feature that the claimed antibodies are specific for a caspase-14 polypeptide comprising SEQ ID NO:2. The polypeptide sequence described by Rasmussen *et al.* is not a caspase-14 polypeptide comprising SEQ ID NO:2, so any antibodies produced against the polypeptide of Rasmussen *et al.* would clearly not be specific for a caspase-14 polypeptide comprising SEQ ID NO:2. Accordingly, Applicants submit that Rasmussen *et al.* fails to render the claimed antibodies.

Furthermore, Applicants submit that even assuming *arguendo* that Rasmussen *et al.* taught each element of the claimed invention, Rasmussen *et al.* fails to render the claimed invention obvious, since the reference fails to provide the requisite teaching or suggestion of the desirability of the claimed invention. Applicants note that the mere fact that the teachings of the prior art *can* be combined or modified, or that a person having ordinary skill in the art is *capable* of combining or modifying the teachings of the prior art, does not make the resultant combination *prima facie* obvious, as the prior art must also suggest the desirability of the combination (*see, e.g., In re Mills,* 16 USPQ2d 1430 (Fed. Cir. 1990); *In re Fritch,* 23 USPQ2d 1780 (Fed. Cir. 1992)). Applicants note that Rasmusen *et al.* describes the sequencing of multiple proteins present in normal human keratinocytes, in an effort to integrate protein and DNA sequence information, identify protein sequence similarities, and prepare DNA probes to clone the genes corresponding to these proteins (page 960, lines 1-9). However, Rasmussen *et al.* fails to teach or suggest any advantage or desirability of producing antibodies specific for the identified polypeptides. Accordingly, Applicants submit that Rasmussen *et al.* fails to provide the requisite teaching or motivation to produce the claimed antibodies and respectfully request that this basis of rejection be withdrawn.The Director is authorized to charge any additional fees

due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that all of the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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